RISK ASSESSMENT AND SCIENCE SUPPORT BRANCH

ANTIMICROBIAL DIVISION

EFFICACY REVIEW - II

EPA Reg. No. or File Symbol 675-LL

EPA Petition or EUP No. None

Date Division Received 9-23-97

Type Product Hospital Disinfectant

MRID No(s) 443868-1-7-8-9-10

Product Management Team PM34

Product Name Lysol Brand Disinfectant S.A. Cleaner

Company Name Reckitt & Coleman

200.0 Introduction:

200.1 **Uses:**

Hospital Disinfectant

200.2 **Background Information:**

The registrant has submitted efficacy data to add additional microorganisms and proposed labeling.

200.3 **Factors Affecting Amount/Type of Data Required:**

None

201.0 Data Summary

None

201.1 **Abstract of Test Reports:**

None

201.2 **Brief Description of Tests:**

1. "Disinfectant Efficacy Testing Hospital Type Disinfectant Activity In The Presence of Organic Soil" by T. Cusack of Reckitt & Colman, Montvale, NJ; dated 2/23/97, MRID No. 443868-07.

2. "Disinfectant Efficacy Testing Activity in The Presence of Organic Soil" by V. Pelov of Reckitt & Colman, Montvale, NJ; dated 5/9/97, MRID No. 443868-08.

3. "Disinfectant Efficacy Testing Activity in The Presence of Organic Soil" by V. Pelov of Reckitt & Colman, Montvale, NJ; dated 5/9/97, MRID No. 443868-09.

4. "Disinfectant Efficacy Testing Activity in The Presence of Organic Soil" by V. Pelov of Reckitt & Colman, Montvale, NJ; dated 5/9/97, MRID No. 443868-10.

201.3 **Data Summaries**

None

201.4 **Other Summarized Results:**

See Recommendations under 202.0.

202.0 Recommendations

202.1 Efficacy Supported By The Data:

1. ▒Disinfectant Efficacy Testing Hospital Type Disinfectant Activity In The Presence of Organic Soil▒ by T. Cusack of Reckitt & Colman, Montvale, NJ; dated 2/23/97, MRID No. 443868-07.

The submitted efficacy data developed by the AOAC Germicidal Spray Test Method and the AOAC Phenol Coefficient Test Method appear adequate to support effectiveness of the product as a hospital disinfectant against Pseudomonas aeruginosa ATCC 15442, Salmonella choleraesuis ATCC 10708 and Staphylococcus aureus ATCC 6538 on hard, nonporous surfaces when undiluted in the presence of 5% blood serum for a contact time of ten minutes at 23°C.

2. ▒Disinfectant Efficacy Testing Activity in The Presence of Organic Soil▒ by V. Pelov of Reckitt & Colman, Montvale, NJ; dated 5/9/97, MRID No. 443868-08.

The submitted efficacy data developed by the AOAC Germicidal Spray Test Method appear adequate to support effectiveness of the product as a disinfectant against Enterococcus faecium ATCC 6569 on hard, nonporous surfaces when undiluted in the presence of 5% blood serum for a contact time of ten minutes at 23°C.

3. ▒Disinfectant Efficacy Testing Activity in The Presence of Organic Soil▒ by V. Pelov of Reckitt & Colman, Montvale, NJ; dated 5/9/97, MRID No. 443868-09.

The submitted efficacy data developed by the AOAC Germicidal Spray Test Method appear adequate to support effectiveness of the product as a disinfectant against Enterococcus faecalis ATCC 828 on hard, nonporous surfaces when undiluted in the presence of 5% blood serum for a contact time of ten minutes at 23°C.

4. ▒Disinfectant Efficacy Testing Activity in The Presence of Organic Soil▒ by V. Pelov of Reckitt & Colman, Montvale, NJ; dated 5/9/97, MRID No. 443868-10.

The submitted efficacy data developed by the AOAC Germicidal Spray Test Method appear adequate to support effectiveness of the product as a disinfectant against Streptococcus pyogenes ATCC 12384 on hard, nonporous surfaces when undiluted in the presence of 5% blood serum for a contact time of ten minutes at 23°C.

203.0 **Labeling:**

The proposed labeling is acceptable. However, the registrant must be informed that on page 3, under the subheading "Kills:" the surfaces to be treated must be identified as hard, nonporous. Currently the registrant has the word nonporous as optional.